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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,937	07/24/2003	Michael Lebner	0156-2004US01	9900

7590 11/01/2005

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EXAMINER
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EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/625,937	LEBNER, MICHAEL	
	Examiner	Art Unit	
	Darwin P. Erez	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-18 and 20-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-18 and 20-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3-18 and 20-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 18 now recite the limitation of "the lower surface of the bridging portion is substantially free of adhesive" which is inconsistent with a prior limitation of "the lower surface of the bridging portion contains less adhesive than the attached portion". The latter limitation implies that the bridging portion contains some amount of adhesives. Therefore, the amended limitation renders the claims vague and indefinite.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 5, 15, 16, 18, 20, 22, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by US 1,969,188 to Spicer.

As to claim 1, Spicer teaches a two part component for closing a wound, as depicted in Fig. 2. Each component comprises a first adhesive backed anchoring member **12a** and one connecting member **13a** (including thread **14**, which acts as a

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bridge), wherein adhesive is applied to the bottom of the connector member **13a** and the lower surface of the bridge/thread is devoid of any adhesive.

As to claim 3, Spicer teaches a pulling element **18** attached to both components.

As to claim 5, Spicer teaches that a piece of paper or uncoated tape may be applied to provide a finger grip (col. 1, lines 48-49). This paper or tape is fully capable of being removed.

As to claim 15, the edge of either component would serve as an alignment indicator relative to the wound or incision cut.

As to claim 16, the folded portion of the anchor serves as a pull bar.

As to claim 18, Spicer teaches a method of closing a laceration, the method comprising the steps of providing a device as recited in the rejection to claim 1; attaching a first component to one side of the wound, attaching a second component to the opposite side of the wound, closing the wound by adjusting the position of the anchoring members, and attaching the connecting members to anchoring members (Fig. 2).

As to claims 20, 22, 32 and 33, see the rejections of claim 3, 5, 15, 16, respectively.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 . USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 4, 6-14, 17, 21, 23-31, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spicer in view of US 6,329,564 to Lebner.

Spicer teaches all the limitations of the claim except for a coding means comprising an observable geometric distinction between the shape of the pulling elements and the shape of the anchoring members, that the coding comprises printed indicia enabling user distinction between pulling elements and anchoring members, that the coding further comprises distinguishing colors. Spicer is also silent with regards to the release liners recited in the claims and the type of material used to form the device.

With regards to claims 4, 6-8, 13, 14, Lebner teaches a wound closure device wherein the device can include wound visual alignment indicators, and further discloses at col. 5, lines 1-21, that the bandage can include indicia (e.g. color, graphic representation, etc.) for the purpose of indicating specific information to the user (e.g. tension).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide any portion of the device of Spicer

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with indicia of various types (such as recited above) in order to indicate any information to the user. As such, the claims are not distinguishable from the prior art.

With regards to claim 9, Lebner teaches a wound bandage formed from vapor-permeable material (col. 3, lines 5-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the device of Spicer with a vapor permeable material, as taught by Lebner, because it would allow for the exchange of air with the skin beneath the bandage.

With regards to claims 10-12, It should also be noted that Lebner teaches release liners in col. 1, lines 48-65. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide release liners to the device of Spicer because it would prevent the device from prematurely adhering to any object prior to applying the device in the wound area. Moreover, it is well known in the art to provide release liners to wound bandages and would be well within the knowledge of one of ordinary skill in the art.

With regards to claims 16 and 17, though the applicant does not clearly state what a pull bar or wound edge bar is, it should be noted that Lebner teaches reinforcements for the device at col. 2, line 60 – col. 3, line 4. Therefore, it would be obvious to one of ordinary skill in the art to use reinforcements in the device of Spicer because the reinforcements would help maintain the orientation of the device when tension is applied.

As to claims 21, 23-31, 33, 34 see the rejections of claims 4, 6-14, 16, 17, respectively.

***Response to Arguments***

8. Applicant's arguments with respect to claims 1, 3-18, 20-34 have been considered but are moot in view of the new ground(s) of rejection.

It should be noted that the applicant did not originally provide the date that was mentioned in the Declaration under Rule 1.131. Therefore, the filing of the Declaration necessitated an updated search and further consideration to provide new grounds of rejections. With regards to the allowable subject matter of the previous office action, the claims are no longer allowable since the independent claims has been amended and that the scope of the invention has changed.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON  
PRIMARY EXAMINER